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CENTRAL FAX CENTER
Application No.: 10/750,376
Docket No.: 01845-22396
JUN 09 2008

REMARKS

In view of the immediately preceding paragraphs, Applicant addresses the issues raised specifically in the November 5, 2007 Office Action as follows.

Rejection under 35 USC §112

Claims 1, 11-15 and 17-20

In the November 5, 2007 Office Action, the Examining Attorney rejected claims 1, 11-15 and 17-20 as failing to comply with the written description requirement. Specifically, the Examining Attorney indicated that the rejected claims, which had been amended to indicate a step (d) for waiting at least 4 hours before administration of indomethacin, adenosyl0L-methionine, selenium and ibuprofen, was not disclosed. More specifically, the Examining Attorney alleged that the range of "at least 4 hours" was not disclosed in the specification.

In response, Applicant submits that the claims, as now amended back to their original state, do not include the limitation of a range of "at least 4 hours." Accordingly, the Examining Attorney's rejection on this issue is now moot and should be withdrawn.

Predictability

The Examining Attorney alleges that predictability of Applicant's claimed invention appears to be low. In the event that "little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling." MPEP §2164.03; See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004). The examples in the specification have sufficient detail to provide one skilled in the art an understanding of what the Applicant considers to be his invention. These examples provide specific dosing regimens that enable one of ordinary skill in the art to readily make and use the invention, and further enable one of ordinary skill in the art to follow the dosing regimes without undue experimentation. In fact, the skilled person could follow the example exactly if he so chose.

In view of the foregoing, the specification provides sufficient detail to make and use the invention, thus rendering it enabling.

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Amount of direction or guidance present and the presence or absence of working examples

In the Office Action the Examining Attorney indicated that "although the specification provides information as to doses, working examples are not sufficient to establish that the claimed process is effective in reducing the effects of Alzheimer's Dementia." In support of this rejection, the Examining Attorney cited the following articles: (1) Normann et al. (2002) *Confirmation and lucidity during conversations with a woman with severe dementia*, and (2) Normann et al. (1998) *Episodes of lucidity in people with severe dementia as narrated by formal carers*. Both articles address case studies regarding episodes of lucidity in Alzheimer's patients. Normann (2002) presents case study data, which indicate that "a supportive attitude in conversation with the patient with severe dementia promotes lucidity." See Normann et al. (2002) Abstract. Likewise, Normann (1998) presents data showing that "most [episodes of lucidity] were said to occur spontaneously when the patients were acting closely together with a carer who did not make demands on them and regarded them as valuable human beings whose behavior was a meaningful expression of their experiences."

These articles feature information pertaining to a caregiver's attitude and the influence thereof on "episodes of lucidity" in an Alzheimer's patient. Accordingly, these articles are unrelated to the issue of whether Applicant's specification, which provides working examples of administering specific types of medications, is sufficient to establish that the claimed process is effective in reducing the effects of Alzheimer's Dementia. As such, the Normann references are not relevant to the issue of enablement and have been improperly applied in this case.

Breadth of Claims and Quantity of Experimentation Needed

The Examining Attorney argues that the claims are broad in that they claim a method of reducing the effects of Alzheimer's Dementia where the last step has an open ended time period of at least 4 hours in which to administer a dose of indomethacin. As set forth above, the claim to which the Examiner is directing this rejection (claim 1) has been amended back to its original status, which does not include the alleged open ended last step. Accordingly, this rejection is moot and should be withdrawn.

In the November 5, 2007 Office Action, the Examiner further maintained the enablement rejection and asserted that Applicant's previously submitted declaration did not provide sufficient

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evidence to show that the method as claimed is ineffective in reducing the effects of Alzheimer's Dementia. It is Applicant's understanding that the rejection based on Applicant's invention being prophetic has been withdrawn as the Examiner accepted the assertion in the Declaration that the working example was not prophetic in nature. See 5-7-08 Office Action, page 3, first paragraph. Accordingly, Applicant understands that the rejection on grounds that Applicant's invention is prophetic has been resolved in favor of Applicant.

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In light of the above, Applicant respectfully submits that pending claims 21-40 (originally filed as claims 1-20) are now in condition for allowance. Therefore, Applicant requests that the rejections and objections be withdrawn, and that the claims be allowed and passed to issue. If any impediment to the allowance of these claims remains after entry of this Amendment, the Examiner is strongly encouraged to call Gary Oakeson at (801) 566-6633 so that such matters may be resolved as expeditiously as possible.

DATED this 9th day of June, 2008.

Respectfully submitted,



Gary P. Oakeson
Registration No. 44266

THORPE NORTH & WESTERN, LLP
Customer No. 20,551
P.O. Box 1219
Sandy, Utah 84091-1219
Telephone: (801) 566-6633